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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,476	03/29/2004	Douglas C. Harrington	17.003001 CON 2	3267
58732	7590	02/21/2008		
CYTYC CORPORATION 250 CAMPUS DRIVE MARLBOROUGH, MA 01752			EXAMINER ROANE, AARON F	
			ART UNIT 3739	PAPER NUMBER
			MAIL DATE 02/21/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/812,476

Applicant(s)

HARRINGTON ET AL.

Examiner

AARON ROANE

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 5, 19, 20, 23, 37, 38 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Vancillie (USPN 5,095,917).

Regarding claims 1, 19 and 37, Vancillie discloses a method of occluding the ovarian pathway of a female body said method comprising the steps of: applying a heating

element (33) to a target segment of the pathway, and operating the heating element to heat the target segment in the pathway; limiting the heating of the target segment by applying power of 0.1 to 5 watts to the heating element for a period of at least about 5 seconds; installing a plug into the target segment of the pathway, see col. 1-6, particularly col. 2, line 28 through col. 3, line 22 and figures 1-6.

Regarding claims 2, 20 and 38 Vancillie further disclose the heating element in the form of at least one electrode adapted for application to the ovarian pathway, inherent as the any one of the electrical connections of 37 with copper wire 33.

Regarding claims 5, 23 and 41, Vancillie further discloses providing the heating element in the form of at least one resistive heating element (33) adapted for application to the ovarian pathway, see copper wire col. 2, line 68 through col. 3, line 4 and figures 1-6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 3, 4, 6-8, 21, 22, 24-26, 39, 40 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vancillie (USPN 5,095,917) in view of Makower (USPN 5,830,222).

Regarding claim 3, 4, 6-8, 21, 22, 24-26, 39, 40 and 42-44, Vancillie discloses the claimed invention except for the use of RF energy, the heating element being at least two electrodes adapted for application to the ovarian pathway, and applying bi-polar RF energy to said electrodes, a microwave heating element, an ultrasound heating element and/or a laser heating element. It is extremely well known in the art to use RF energy with one monopolar electrode, at least two bipolar electrodes, resistive heating, microwave, ultrasound and laser as equivalent/alternate forms of energy delivery modalities. Makower discloses a device and method of treating tissue by energy application and teaches various forms of energy "including but not limited to laser, bipolar or monopolar radiofrequency (RF), microwave, ultrasound, hot-wire, or radiation" may be used as alternate/equivalent energy applications in order to heat tissue, see col. 6, lines 24-29. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Vancillie, as taught by Makower, to use RF monopolar electrodes or RF bipolar electrodes as well as laser, ultrasound and microwave energy delivery as an alternative to RF delivery in order to cause thermal damage and subsequent inflammation to the tissue.

Claims 9, 10, 13, 17, 27, 28, 31, 35, 45, 46, 49 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vancillie (USPN 5,095,917) in view of Zeluff (USPN 4,606,336).

Regarding claims 9, 10, 27, 28, 45 and 46, Vancillie discloses the claimed invention except for the plug being reticulated foam having a pore size of 40-200 microns or 1-20. Vancillie disclose that the plug is an expandable, absorbable plug. However, Vancillie falls short of explicitly reciting the plug is a sponge or foam. Zeluff discloses an apparatus and method for sterilizing female reproductive organs and teaches providing a plug made of an expandable porous structure in order to promote ingrowth of fibroblast and create a hermetic seal at the uterotubal junction, see col. 3, line 28 through col. 4, line 23. Zeluff further discloses that the pore size is "on the order of 2 microns or greater," see col. 4, lines 56-64 and figures 1-12. It should be noted that an expandable porous material meets the claimed foam and reticulated foam structure. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Vancillie, as taught by Zeluff, to make the plug from a porous foam having pore size "on the order of 2 microns or greater" in order to promote ingrowth of fibroblast and create a hermetic seal at the uterotubal junction.

Regarding claims 13, 17, 31, 35, 49 and 53, Vancillie in view of Zeluff disclose the claimed invention of the foam plug in the form of an ePTFE plug, see Zeluff col. 4, lines 42-63.

Claims 11, 12, 15, 16, 29, 30, 33, 34, 47, 48, 51 and 52 rejected under 35 U.S.C. 103(a) as being unpatentable over Vancillie (USPN 5,095,917) in view of Zeluff (USPN 4,606,336) as

applied to claims 9, 10, 27, 28, 45 and 46 above, and further in view of Barbacci (USPN 5,531,741).

Regarding claims 11, 12, 15, 16, 29, 30, 33, 34, 47, 48, 51 and 52, Vancillie in view of Zeluff disclose the use of silicone plugs for tubul occlusion, but fail to recite the silicone plug has a durometer of 1-200 Shore A and/or 60 Shore A. Barbacci discloses a uterine and/or fallopian tube stent and teach providing a stent made of silicone rubber having a durometer of 55 to 70 Shore A in order to provide comfort, see col. 7, lines 28-55, col. 8, line 66 through col. 9, line 11 and figures 1-22. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Vancillie in view of Zeluff, as taught by Barbacci, to provide a plug made of silicone having a durometer of 55 to 70 Shore A in order to provide comfort.

Claims 14, 18, 32, 36, 50 and 54 rejected under 35 U.S.C. 103(a) as being unpatentable over Vancillie (USPN 5,095,917) in view of Zeluff (USPN 4,606,336) as applied to claims 9, 10, 27, 28, 45 and 46 above, and further in view of Brundin (USPN 4,509,504).

Regarding claims 14, 18, 32, 36, 50 and 54, Vancillie in view of Zeluff disclose the claimed invention except for the plug made of an acrylic copolymer. Brundin discloses an apparatus and method for occluding body channels including the female reproductive organs and teaches using an expandable plug (2) made of acrylic copolymers in order to provide a biocompatible seal, see col. 2, lines 18-41 and figures 1-6. Therefore at the

time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Vancillie in view of Zeluff, as taught by Brundin, to provide a plug made of an alternate material in the form of an acrylic copolymer in order to make a biocompatible seal.

Response to Arguments

Applicant's arguments, see page 11, last paragraph through the first full paragraph on page 13, filed 2/8/2007, with respect to the rejection(s) of claim(s) 1, 2, 19, 20, 37 and 38 under 35 U.S.C. § 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Vancillie (USPN 5,095,917) which fully meets the claims.

This action is NON-FINAL due to Application's persuasive arguments.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON ROANE whose telephone number is (571)272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit
3739

Aaron Roane
February 11, 2008

/A. R./
Examiner, Art Unit 3739